Attachment 4

510(k) Summary

Prepared:	April 5, 2002
TRADE NAME	TruLine™
GENERIC NAME	Catheter, Intravascular, Therapeutic, Short-Term
CLASSIFICATION	Class II (21 CFR 880.5200)
SUBMITTED BY	Micro Therapeutics, Inc. **CONTACT** Tom Daughters 2 Goodyear Regulatory Affairs Irvine, CA 92618 (949) 837-3700
PREDICATE DEVICE	TruLine™ Reinforced Valved Infusion Catheters
DEVICE DESCRIPTION	The MTI TruLine™ Reinforced Infusion Catheter is a single-lumen plastic catheter designed to be introduced over a guidewire into the vasculature. Once positioned, various pharmacological agents may be delivered through a standard luer lock adapter at the proximal end. The infusion area is indicated by distal and proximal radiopaque markers to facilitate fluoroscopic visualization. The reinforced Infusion catheters are available in a variety of infusion lengths.
INDICATIONS FOR USE	The MTI Reinforced Infusion Catheter is intended to be used for the controlled selective infusion of physician-specified pharmacologic agents or radiopaque contrast media into the general vasculature.
TESTING	Biocompatibility of the MTI TruLine™ Reinforced Valved Infusion Catheter was verified in accordance with ISO 10993-1, Biological Evaluation of Medical Devices. Test results confirmed biocompatibility of the catheter when tested as an external communicating, blood contact, limited exposure (<24 hrs) device. In-vitro performance testing of the MTI TruLine™ Reinforced Infusion Catheter included dimensional inspection, tensile strength tests, burst pressure tests, flow rate tests, cyclic fatigue tests and performance under simulated conditions. All testing yielded acceptable results.
SUMMARY OF SUBSTANTIAL EQUIVALENCE	The MTI TruLine™ Reinforced Infusion Catheter is substantially equivalent to the predicate device in intended use and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2002

Mr. Tom Daughters
Director, Regulatory Affairs
Micro Therapeutics, Incorporated
2 Goodyear
Irvine, California 92618

Re: K021139
Trade/Device Name: TruLine™ Reinforced Valved Infusion Catheter
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: April 5, 2002
Received: April 9, 2002

Dear Mr. Daughters:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number (if known): K021139

Device Name: TruLine™ Reinforced Valved Infusion Catheter

Indications for Use: The MTI Reinforced Infusion Catheter is intended to be used for the controlled selective infusion of physician-specified pharmacologic agents or radiopaque contrast media into the general vasculature.

Patricia Cucuzza

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021139

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over the Counter Use** _____

(Per 21 CFR 801.109)